Consent Form Template – Full Committee Review Studies

General Instructions: *The consent form is one part of an ongoing dialogue between researchers and participants. Please describe the consent process in the lay summary.*

- *The consent form should be written at an eighth grade level. Avoid dense paragraphs using lengthy sentences. Use 'bullets' and tables to clearly explain topics such as what the study involves and financial considerations.*

- *Suggested wording is contained in the consent template below. Please carefully review all the language to ensure correct information specific to your project is relayed to potential participants.*

- *The bold questions are to be kept as part of the consent form. The information after the question should be edited/deleted/revised to be specific to your project.*

- *Research records (specifically the signed consent form must be maintained for six years after the completion of the study).*

- *Please number the pages of the consent form..*

- *Use 12 point Palatino font as is used in this template (or Times New Roman for older versions).*

- *Please leave a minimum of a 1.25 inch margin on the bottom of each page for the CPHS stamp.*

- *The CPHS office will 'pre-review' a consent form at anytime via email. Please email to nhcphs@mhcgm.org.*

- *This consent form template language focuses on clinical treatment related research. Please edit wording as appropriate for your study. Contact Margaret Almeida at the CPHS Office 668-4111 ext. 5301, if you need help.*

HIPAA: Health Insurance Portability and Accountability Act.
As of April 14, 2003 all consent forms must contain the following information.
Please carefully review the wording in your consent form to ensure all elements are adequately described. We have provided some sample template wording however since each study is unique the researcher must complete the consent form such that the methods and processes contained in the protocol and/or contract are translated to the patient.

1. Description of Health Information to be gathered.
2. Identification of Person authorized to disclose [e.g. researcher, research team]
3. Identification of Recipient [e.g. sponsor, CRO]
4. Description of Purpose(s)
5. Expiration date - "end of research study," "none," or similar language is sufficient if the disclosure is for research, including for the creation and maintenance of a research database or research repository
6. Statement of Right to Revoke
7. (In) Ability to Condition Treatment on the Authorization statement
8. Statement Regarding Re-disclosure
9. Remuneration for Marketing Activity (if applicable)
10. Dated Patient Signature
11. If signed by Personal Representative, a description of that person's authority

CONSENT TO PARTICIPATE IN RESEARCH

Name of Organization:

Study title:

Primary Investigator:

Sponsor: (*List all funding sources)*

You are being asked to participate in a research study. Your participation is voluntary.

Note: if the study includes minors, add a sentence: "You" in this study may refer to your child to be enrolled in the study.

Your decision whether or not to participate will have no effect on the *quality of your medical care, academic standing, job status, quality of rehabilitative or social support programs etc. (whatever phrase is appropriate).* Please ask questions if there is anything you do not understand.

What is the purpose of this study?

The purpose of the study is .....*explanation in **lay** language of the basic purpose of the study.*

Are there any benefits from participating in this study?

First sentence as appropriate to the specific study: choose one of the following:
You will not benefit from being in this research study.
There is little chance you will benefit from being in this research study.
You may not benefit from being in this research study.

Second sentence, if applicable:
It is possible you will benefit because.....

Third sentence, if applicable:
We hope to gather information that may help people in the future.

What does this study involve?

*Briefly explain the following in **lay** language:*

- *Any tasks, procedures, therapies, or tests;*
- *Whether medications or devices are being used in ways that are not FDA approved, if applicable;*
- *The use of placebo condition, if applicable;*
- *Whether all subjects will receive the same treatment, if applicable;*
- *The process of randomization, if applicable;*
- *Whether or not subjects will be able to continue to take study medication or use devices after the conclusion of the study, if applicable;*
- *The types of questions that will be asked, particularly if there are questions about sensitive areas such as: HIV status, substance use, sexual practices, or illegal behavior;*
- *The expected total duration of a subject's participation.*

Use tables and/or charts to simplify procedures. If there are multiple study groups, clarify this by listing the groups as follows:
Group A - will receive xxx
Group B - will receive xxx

How is this different from what will happen if you do not participate in this study?

In lay language, provide description of how study participation differs from what will happen if subjects do not participate, including a statement of alternative procedures or courses of treatment available *Explain if research therapy can be obtained off study.*

What are the risks involved with being enrolled in this study?

Do not list every possible side-effect or complication that could occur, but certainly be accurate. Comprehension is usually inversely related to the amount of information presented so include only the things that you think are important for a potential participant to remember. It may be desirable to list a small number of potential problems here in the consent document and then attach a more detailed list on a separate piece of paper. Use wording such as: Attached to this consent document is a more detailed description of the known side effects for drugs and procedures which will be used in this research study.

With drug studies involving a multi-drug regimen, list the problems associated with the entire regimen rather than providing separate information for each individual medication. Whenever possible, you should estimate the probability that a problem will occur. Words such as "common," "unlikely," "occasionally," or "rare" may be used when it is not desirable to use numerical estimates. Whenever possible, use a table format to summarize risk information. Be sure to include risks of being in a placebo or observation group.

Note: When research involves therapy or procedures that would be recommended if medical care is delivered outside the setting of a research protocol, it is appropriate to explain that the risks associated with such therapy will not be avoided by electing not to participate in the study.

Sample wording:
We can not be sure how your body may respond to the (medications or procedures) used in this study. The researchers will discuss possible difficulties and the chances that they will happen. Unknown problems may happen. Problems may range from a minor inconvenience or may be so severe as to result in death *(indicate highest severity level if death is not applicable)*. You should report any problems to your doctor or to the director of this study**:** *(PI name and phone number).*

Example of table format:

DRUG(S)	PROBLEM	CHANCE IT WILL HAPPEN TO YOU % chance or common, unlikely, occasionally, rare

If applicable include the following section, include suggested wording as appropriate:
Pregnancy:

The risks of *name(s) of drug(s)* to an unborn child are unknown. Pregnant women may not take part in this research study. Pregnancy tests will be conducted on all women of child bearing potential.....every....xxx..... The sponsor, or your insurance company (indicate which one) will pay for pregnancy tests.

In order to take part in this research study, all *women of child bearing potential* are required to use a medically approved method of birth control (diaphragm, IUD, progesterone implants or injections, or double barrier method). Please discuss these options with the researcher.

For females: If you become pregnant, you must notify *(name to notify) immediately* and you will be required to discontinue any further treatment under the conditions of this study.

For males: If your partner becomes pregnant while you are on this study, you should inform *(name to notify) of* this event immediately.

Genetics:

If the study might involve obtaining biological samples for the purpose of genetic testing, then a separate consent form may be considered and a statement explaining the following items is necessary. Please see the website link "Genetics – Standard Language" for more details. If the project does not involve genetics then continue on to "Other Items You Should Know".

- The nature and timing of information subjects will be given as a result of their genetic testing including:
- Whether the subject can choose not to receive this information; and whether there will be pre- and post-test counseling;
- If applicable, that subjects might find out information about themselves or their family that they do not want to know, or that they might be uncomfortable knowing;
- If applicable, that information about a subject might be learned by others in his or her family;
- If applicable, that information subjects learn or information generated about them during the study might compromise their insurability;
- If applicable, that submitting insurance claim forms for reimbursement for costs of genetic counseling or procedures whose costs are not covered by the protocol might compromise subjects' insurability or confidentiality;
- The manner in which the confidentiality of the results of genetic testing will be protected;
- If applicable, that the genetic information will be disclosed to the subject's physician;
- The manner in which genetic samples will be stored, used and disposed; and
- Whether or not the subject can revoke his or her consent to future use and disposal of genetic samples;

Other important items you should know:

Complete each section as appropriate

- Your decision whether or not to participate in this study, or a decision to withdraw will not involve any penalty or loss of benefits to which you are entitled.
- *If applicable*: You will not receive any compensation if the results of this research are used towards the development of a commercially available product.
- **Withdrawal from the study:** You may choose to stop your participation in this study at any time. *{If withdrawal could affect medical treatment describe how, here}*. Your decision to stop your participation will have no effect on the *quality of medical care, job status, etc. (whatever phrase is appropriate).*

Provide information about the procedure the subject should use in withdrawing from the study (i.e. notify the investigator, tell study staff, etc)

If applicable, add here information about possibility of termination by investigator without participant consent.

- **New Information:** To the best of our ability, any significant new findings during this research study will be made known to you. You can then decide if you want to continue in this study.

Data Collection

The data collected in this study includes: *describe here*

The data collected in this study will be used for the purpose described in this form. Patient identifiable data will not be released beyond that required for the purposes of conducting this research study. By signing this form, you are allowing the research team access to your medical records. The research team includes the researchers listed in this consent form and other personnel involved in this study at *name of facility* and *(if applicable)* other entities as described in the "Confidentiality" section of this consent form.

If you chose to withdraw from the study, you may revoke your approval for the use of your future medical information. To do this, you must contact the researcher in writing *(insert name and address of contact person)*.

Data which has already been collected will be maintained with the research records.

Explain how long data will be maintained: Examples:

Data gathered from this study will be maintained for as long as the sponsor needs to obtain approval from the FDA.

Data gathered from this study will be maintained indefinitely or as required by federal or state regulations.

If there are limits to the patient access to research records describe here: Example:

During the course of this study participants may not have access to research records.

If you chose, you may request this information after the research is completed.

- **Confidentiality:** Every effort will be taken to protect the names of the participants in this study. *(Describe methods to be used: coding, grant of confidentiality, etc.)* However, there is no guarantee that the information cannot be obtained by legal process or court order.

Describe any risks to confidentiality that are a part of the study and protections used to maintain confidentiality.

If research is being sent outside of your organization, describe here.

Describe as applicable who may have access to research data:

Example:
Research data may be shared, as required by law, with *(name of your organization)* authorities and.....
The New Hampshire CPHS authorities and certain federal agencies such as *Examples: The Food and Drug Administration, US Department of Helth and Human Services and the sponsor of this study, XYZ Co., will have access to records related to this research. The informed consent document shall indicate whether or not data gathered in the course of research will be shared with the subject's treatment providers.*

If you give us information about the abuse/neglect of a minor or incapacitated adult or make threat of harm to self or others, we may have to report this information to the proper individuals.

If the research is sponsored or if the data is being sent anywhere outside of your organization describe in some detail: The sponsor of the study, xxx, and any corresponding entities involved in the monitoring of this study (*name of CRO if applicable*) or Data and Safety Monitoring Committee if applicable, will also have access to this research data. *(If applicable)* These organizations do not have a regulatory obligation to protect the data. (*However if the data being released is not patient identifiable or the sponsor agrees not to re-disclose patient identifiable information, a statement to that effect should be included here*).

If there is a federal certificate of confidentiality indicate so, here

- **Number of participants:** We expect (#) of participants to enroll in this study here, and (#) nationwide.

<u>Who should you call with questions about this study?</u>
Questions about this study may be directed to your doctor or to the researcher in charge of this study: *Provide the number to call and an explanation of the days and times that someone is available to the subject. Example:* Dr. xxx can be reached at (603) 650-xxxx Monday – Friday between the hours of 9:00 to 5:00.
If Dr. xxx is not available, other *members of the section of xxx will be available to answer your questions at any time.*

If you have general questions about being a research participant, you may call The Office of the Committee for the Protection of Human Subjects of The New Hampshire Committee for

The Protection of Human Subjects at the Mental Health Center of Greater Manchester (603) 668-4111 ext. 5301.

What about the costs of this study?

Clearly explain the costs which may be charged to the participant/ insurance co. versus the charges which will be paid for by the sponsor. Suggested wording:

You will not be charged for any test that is completed solely for this study. The sponsor of the study, _____, will pay for all costs associated with the study. The tests you will not be charged for include.....

The parts of your care which would normally be done as standard treatment such as..... will be billed to you or your insurance company.

*Unless **ALL** charges (including standard care) are to be paid by the sponsor, the following is **required:***

Your insurance company may not pay for medical treatment that is part of a research study.

Will you be paid to participate in this study?

Yes or No. If yes, describe payment schedule / travel reimbursement etc. This must correspond to the description in the protocol summary.

What happens if you get sick or hurt from participating in this study?

SPONSOR (SPONSOR NAME) POLICY: The sponsor of this research is XYZ Company. If you develop an illness or an injury happens because you are in this research study the XYZ Company will**.....***enter the appropriate information regarding the level of liability the sponsor will assume in case of research related injury or illness.*

If you have any questions about the legal responsibility of NH DHHS, please call the NH DHHS CPHS at 603-668-4111 ext. 5301 between the hours of 8:30 A.M. and 5:00 P.M. on Monday through Friday.

CONSENT

I have read the above information about *(name of study),* and have been given an opportunity to ask questions. *If applicable: I have been offered the opportunity to discuss participation in the study with a family member or concerned others*. I agree to participate in this study. I have been given a signed copy of this consent document for my own records.

SIGNATURE OPTIONS (choose one block):

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If study includes competent participants only:

_____	_____	_____
Participant's Signature	Date	Printed Name

I have fully explained this research to the subject and have answered any question(s) he or she has asked. I believe the subject understands the study and is able to give voluntary consent.

_____	_____	_____
Researcher's Signature	Date	Printed Name

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If your study receives IRB approval to include participants with legally authorized surrogate decision makers, include the following lines to signature section as the IRB has indicated is appropriate.

_____	_____	_____
Participant's Signature	Date	Printed Name

If participant is not competent to provide informed consent, please sign as appropriate:

_____	_____	_____
Durable Power of Attorney for Health Care	Date	Printed Name

Or

_____	_____	_____
Legally Court-Appointed Guardian	Date	Printed Name

I have fully explained this research to the subject and their legally-authorized-representative. I have answered any question(s) they have asked. I believe the subject and their legally-authorized-representative understands the study and is able to give voluntary consent.

_____	_____	_____
Researcher's Signature	Date	Printed Name

If your study may include minors add the signature line for assent. The parent or legal guardian should sign as Legally Authorized Representative and the minor should sign the Assent line.

_____	_____	_____
Legally Authorized Representative	Date	Printed Name
_____	_____	_____
Assent of Minor	Date	Printed Name

I have fully explained this research to the minor subject and their legally-authorized-representative. I have answered any question(s) they have asked. I believe the subject and their legally authorized representative understands the study and is able to give voluntary consent.

_____	_____	_____
Researcher's Signature	Date	Printed Name